65331-4

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

7 26 2011

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 26, 2011

Karen C. Cunningham Head, Regulatory Affairs Merial Limited 3239 Satellite Blvd. Building 500, Office 113 Duluth, GA 30096-4640

Subject:

Application for Pesticide Amendment Frontline Plus for Cats EPA Reg. No. 65331-4 Your Submission Dated May 24, 2011 Decision No: 450696

Dear Ms. Cunningham:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

If you have any questions contact Driss Benmhend at 703-308-9525 or by e-mail at: <u>Benmhend.driss@epa.gov</u>.

Sincerely,

Ph. & C. DC

Richard Gebken Product Manager 10, Insecticide Branch Registration Division (7505P)

Enclosure: Label stamped "Accepted"





BACK

FRONTLINE® PLOTS FOR

For use ONLY on CATS & KITTENS 8 weeks or older: Fast-acting, long-lasting, waterproof treatment and control of fleas, flea eggs & larvae, ticks, chewing lice and mosquitoes.

ACTIVE INGREDIENTS
fipronil:
(S)-methoprene
INERT INGREDIENTS
TOTAL
KEEP OUT OF REACH OF CHILDREN
OAUTION

CAUTION FRONTLINE® Plus for Cats:

Fleas

- Kills fleas, flea eggs and flea larvae Prevents all flea stages (eggs, larvae, pupae)
- from developing Stops existing infestations and prevents
- establishment of new infestations Kills fleas which may cause flea allergy

dermatitis

Ticks Kills all life stages of ticks (larva, nymph and adult), including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), Ione star ticks

(Amblyomma americanum) and deer ticks (Ixodes scapularis)

 Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases Lice

Rapidly eliminates chewing lice infestations Mosquitoes

- Kills mosquitoes FRONTLINE Plus is approved for use on all cats, including: • Breeding, pregnant, and lactating queens
- Kittens as young as 8 weeks

One spot application is all that's needed: FRONTLINE Plus spreads from the single point of application, rapidly covering the entire cat and localizing in the hair, on the surface of the skin and in the sebaceous glands. These glands act as a reservoir, continuously replenishing FRONTLINE Plus onto the skin and hair coat, so it keeps

working even if the cat gets wet. Fleas, flexs, and chewing lice are killed quickly after coming into contact with a treated cat. Fleas and ticks do not need to bite the cat in order to die.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND DEFORM TO ADD AND THE FORM CONFERENCE PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS, DO NOT USE ON OTHER ANIMALS. To kill fleas, flea eggs & larvae, ticks, chewing lice and mosquitoes apply FRONTLINE Plus for Cats as follows:

OPEN Applicator Hold upright with foil side toward you and snap applicator tip

APPLY FRONTLINE Plus Part the cat's hair above the shoulder blades, at the

base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the cat's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry. FRONTLINE Plus for Cat's is approved for use

on all cats, including breeding, pregnant, and lactating queens and kittens as young as 8 weeks. FRONTLINE Plus remains effective even after bathing, water immersion, or exposure to sunlight.

FREQUENCY OF APPLICATION When used monthly, FRONTLINE Plus completely breaks the flea life cycle and controls tick and chewing lice infestations. Do not reapply FRONTLINE Plus for 30 days.

FRONTLINE Plus kills adult fleas, flea eggs, and flea larvae for up to six weeks. FRONTLINE Plus

also prevents development of all flea stages for up to six weeks. FRONTLINE Plus can control fleas for up to six weeks, however, if there is a high risk of reinfestation or if the cat has fleas which may cause flea allergy dermatitis, a once monthly application may be needed. FRONTLINE Plus kills ticks for at least one

month. A once monthly application is recommended where tick control is needed. FRONTLINE Plus kills all life stages of ticks (larva, nymph and adult). FRONTLINE Plus kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, asmosis and other tick-borne diseases FRONTLINE Plus kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is

FRONTLINE Plus kills mosquitoes within 24 hours for up to 14 days, and within 48 hours for up to 28 days with a monthly application

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage STORAGE. Store unused product in original

container only, out of reach of children and animals

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Nonrefillable container. Do not reuse or refill this DISPOSAL. If empty: container. Place in trash or offer for recycling if available.

FIRST AID

INSIDE | PANELS

Have the product container or label with you when calling a poison control center or doctor, or going

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice

FRONT

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tohacco

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-660-1842, Monday-Friday, 8am-8pm EST.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame

WARRANTY

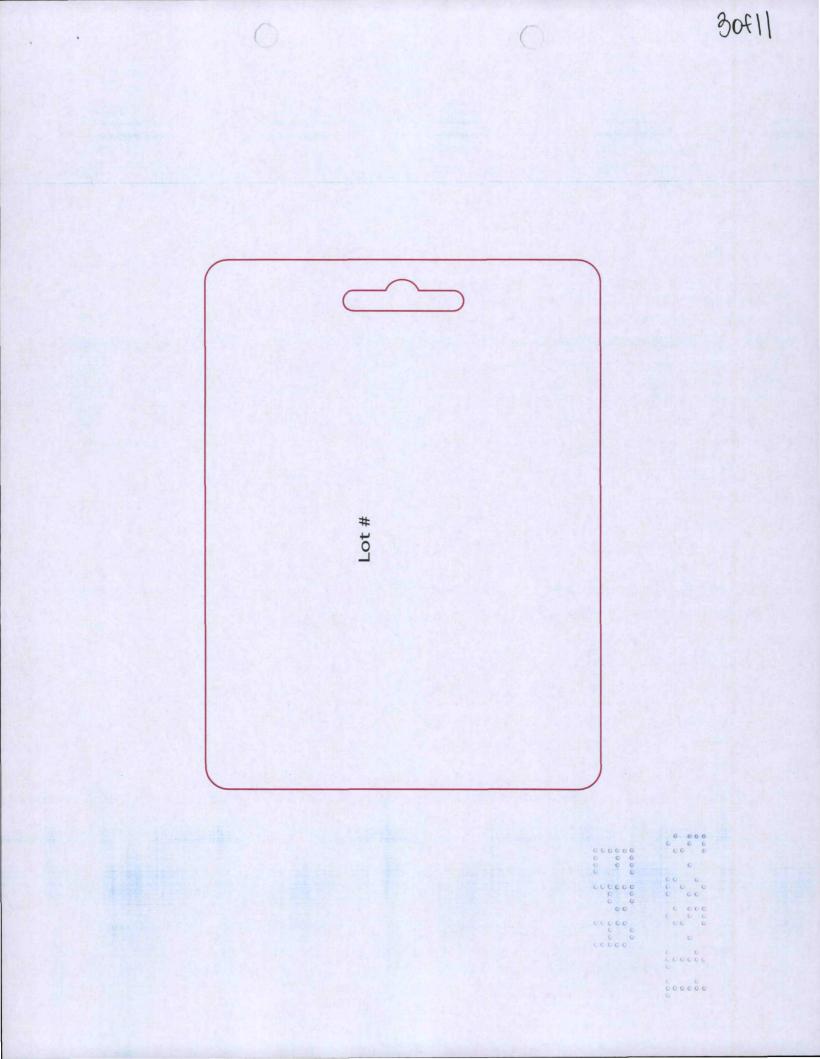
To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and handling of this material when such use and handling are contrary to label instructions.

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3239 Satellite Blvd. Duluth, GA 30096-4640, USA BFRONTLINE is a registered to comark of Merial. 2017 (J.c. ic. L.m.)ed, Duluth, GA. Ail rights reserved.

ACCEPTED JUL 2 6 2011 Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the 1112009-09h32 SK DULUTH pesticide registered under: 09/16/2010 - TR

FPA. Ren No. 65331-4





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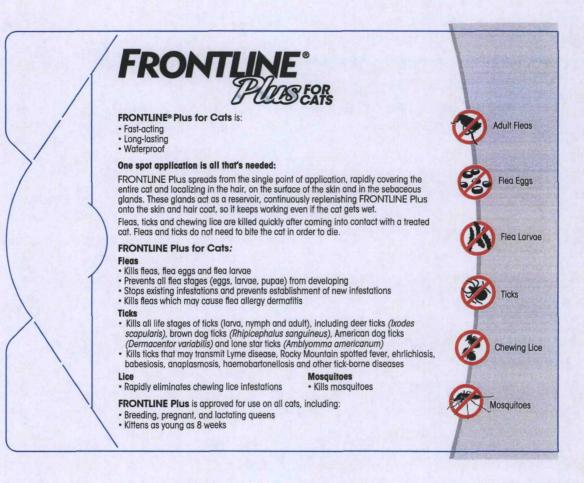
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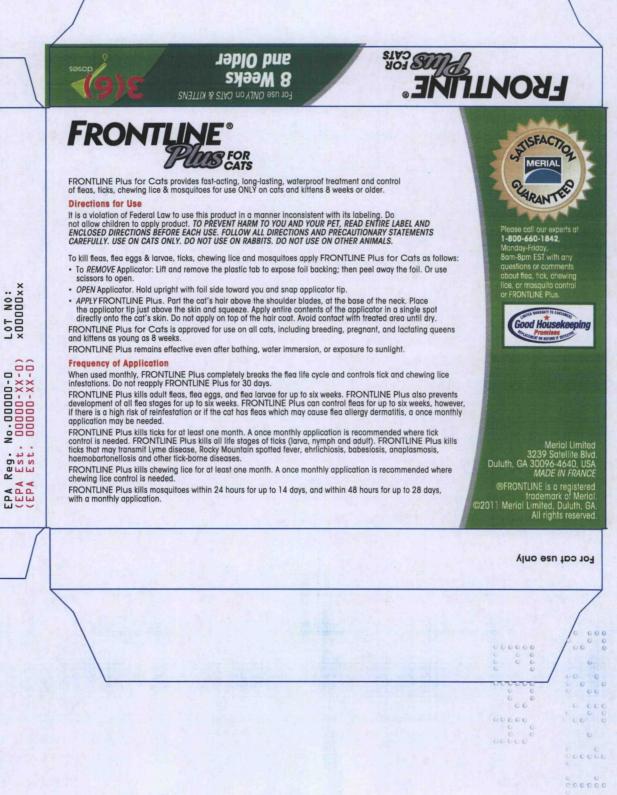
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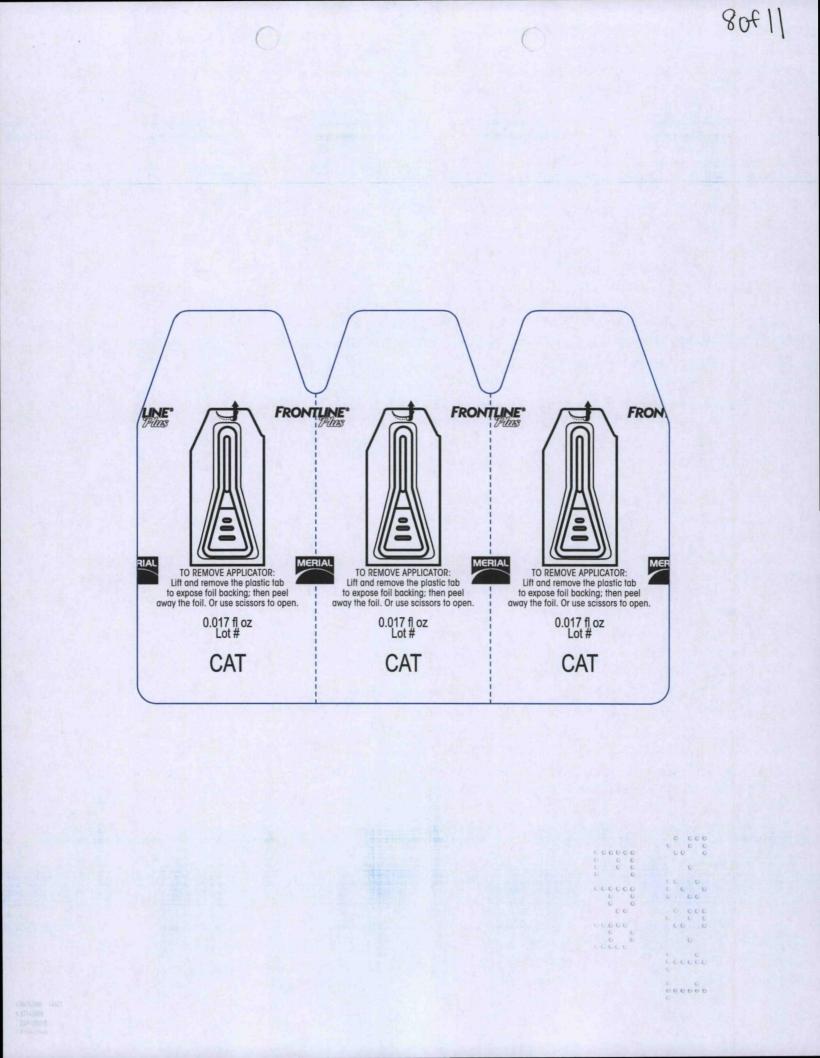
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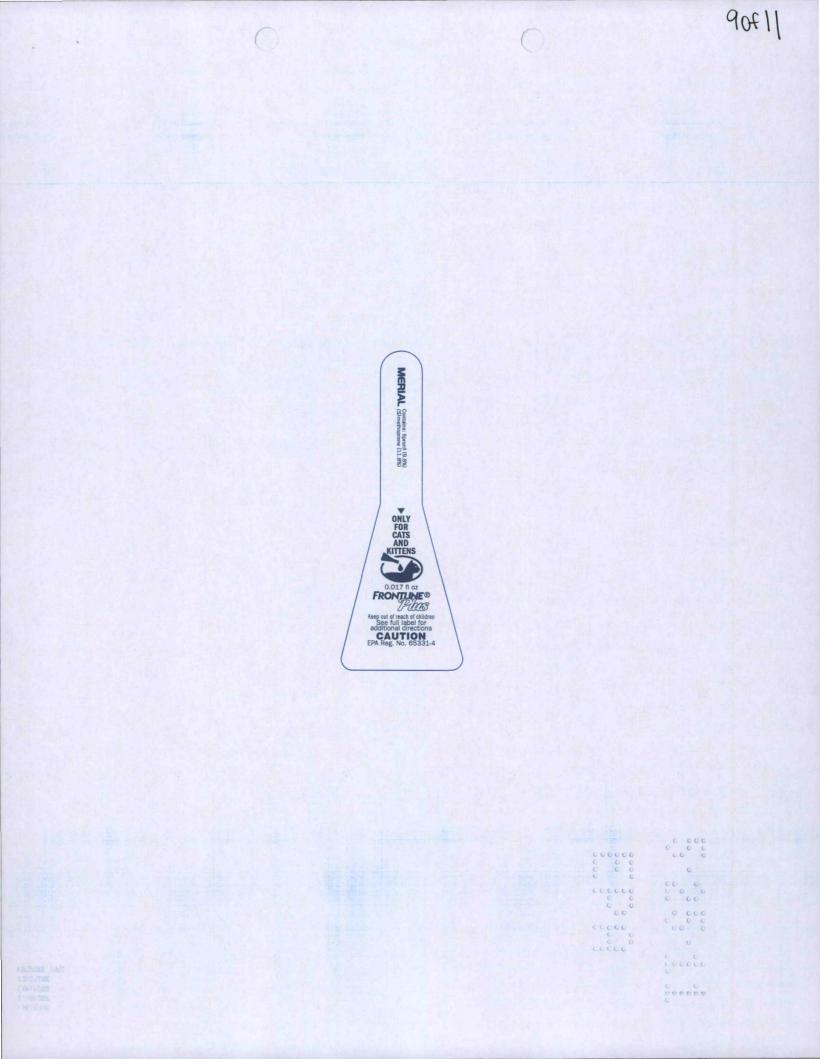


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For use ONLY on CATS & KITTENS 8 weeks or older:

Fast-acting, long-lasting, waterproof treatment and control of fleas, flea eggs & larvae, ticks, chewing lice and mosquitoes. ACTIVE INGREDIENTS

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

FRONTLINE® Plus for Cats: Fleas

- Kills fleas, flea eggs and flea larvae
 Prevents all flea stages (eggs, larvae, pupae) from developing
 Stops existing infestations and prevents establishment of new
- infestations
- Kills fleas which may cause flea allergy dermatitis
- Ticks
- Kills all life stages of ticks (larva, nymph and adult), including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), Ione star ticks (*Amblyomma* americanum) and deer ticks (Ixodes scapularis)
- · Kills ticks that may transmit Lyme disease, haemobartonellosis,
- ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases Lice
- Rapidly eliminates chewing lice infestations
 Mosquitoes
- Kills mosquitoes

FRONTLINE Plus is approved for use on all cats, including:

Breeding, pregnant, and lactating queens

 Breeding, pregnant, and lactating queens
 Kittens as young as 8 weeks
 One spot application is all that's needed:
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DIRECTIONS FOR USE

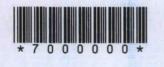
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To kill fleas, flea eggs & larvae, ticks, chewing lice and mosquitoes apply FRONTLINE Plus for Cats as follows:

To REMOVE Applicator: Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open. • OPEN Applicator

Hold upright with foll side toward you and snap applicator tip. • APPLY FRONTLINE Plus

Part the cat's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the cat's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.



FRONT

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Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases.

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COMBUSTIBLE: Do not use or store near heat or open flame. WARRANTY

To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of uce and handling of this material when such use and handling are contrary to label instructions.

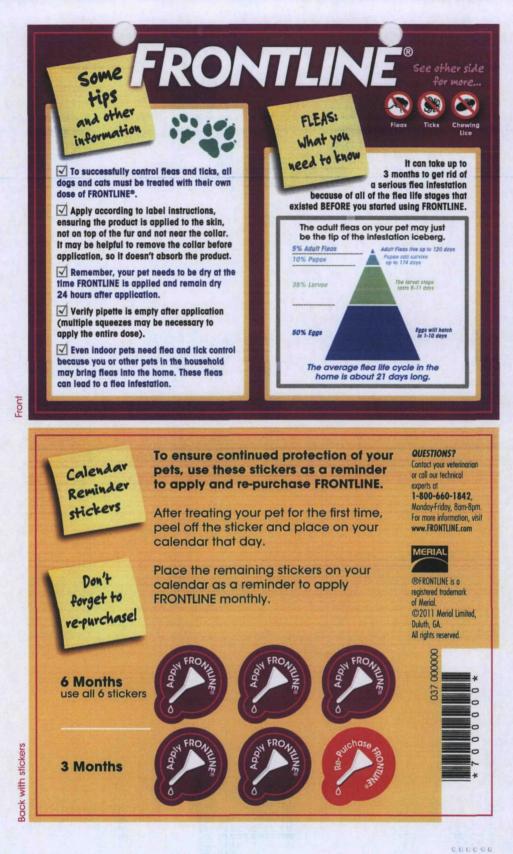
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